

This Request for Continued Examination is submitted in response to the Final Action dated August 13, 2003.

### **Remarks**

No further amendments are presented.

Claims 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166, and 168-185 remain in the application.

Enclosed is a check for \$1190 to cover both the fee for a Request for Continued Examination, and the fee for a two-month extension of time, to extend the time for response from November 13, 2003 to January 13, 2004. (37 C.F.R. § 1.136(a)(3)). If this amount is incorrect, please refer to the Deposit Account Authorization previously filed for this application. If any additional extension of time is required, please consider this paper a petition for the total extension of time required.

Reexamination and reconsideration of the application, as amended, are respectfully requested.

Topic numbers in the headings below (e.g., "7" in the heading immediately below) correspond to those appearing in the August 13, 2003 Office Action. Topic numbers omitted below (e.g., 1-6) are believed not to require any response from the Applicant.

### **7. The Written Description Rejection**

All Claims were again rejected as containing subject matter that lacks an adequate written description in the specification. Some of the reasons given in the prior Office Action in support of this ground of rejection appear to have been withdrawn or to have been made moot.

If the undersigned has correctly understood the August 13, 2003 Office Action, then it appears that two principal reasons underlying this rejection remain, two grounds of rejection that were not withdrawn in response to Applicant's May 16, 2003 Amendment. For the reasons given below, it is respectfully submitted that both of these remaining grounds of rejection should be withdrawn: **(a)** An assertion that the herbicide resistance mechanism had

not been fully characterized. (b) An assertion that it was not clear how to distinguish the claimed herbicide-resistant rice plants (e.g., “a derivative of the plant with ATCC accession number PTA-904”) from other herbicide-resistant rice plants.

***(a) The specification accurately describes the herbicide resistance mechanism.***

Applicant does not concede that the first point (the nature of the resistance mechanism) is properly a written description question. Nevertheless, to the extent that the topic might be germane, it is respectfully submitted that the herbicide resistance mechanism of PTA-904 is fully and accurately described in the specification.

The Office has pointed to one statement in the specification that, taken out of context, might appear to support a different conclusion. The August 13, 2003 Office Action at page 3 cites the third paragraph of page 7 of the specification as an admission that “the resistance mechanisms of the new rice lines have not yet been fully characterized.”

The specification as filed refers to a large number of sources of herbicide resistance in rice. Some 22 lines of rice were deposited with ATCC, and generic claims to herbicide resistance in rice were also presented in the application as filed. See, e.g., the paragraph bridging pages 9 and 10 of the specification; the first full paragraph on page 11; and Claims 1 and 62 as originally filed.

In the interest of expediting the prosecution of Claims that would cover the initial commercially-sold embodiments of the invention and their derivatives, a decision was made to narrow the Claims in the present application considerably. Following a January 2, 2003 amendment, all Claims in the present application have referred only to PTA-904 and specified derivatives of PTA-904. (Note that the broader subject matter is being pursued in a continuation application, S.N. 09/934,973.)

Thus the specification describes subject matter that goes beyond the scope of those Claims that are pending in the present application. The “admission” to which the Office has referred should be read in context – in the context of a patent application that discloses numerous other ATCC-deposited rice lines, their derivatives, and generic resistance to

herbicides: “[T]he resistance mechanisms of the new rice lines have not yet been fully characterized . . . .”

Furthermore, this statement should also be read in the context of what immediately follows the portion quoted by the Office: “[I]t is believed that the herbicide resistance of the novel rice lines is most likely attributable to different mutations of the AHAS enzyme . . . .” Page 7, lines 15-16. Then the specification proceeded to describe exactly what assay would be used to confirm the hypothesized resistance mechanism, and also mentioned an alternative assay that might be used instead. Page 7, lines 18-34.

As described in greater detail in the inventor’s December 18, 2002 Affidavit, which was filed in the Office on January 2, 2003, the assay that was described in the specification has in fact been conducted substantially as described in the specification. That assay fully confirmed that the resistance mechanism was as predicted in the specification – namely, the herbicide resistance characteristics of PTA-904 are attributable to a mutant acetohydroxyacid synthase (AHAS), a mutant enzyme that displays direct resistance to imidazolinone herbicides.

Applicant suggests that a better characterization of the statements on page 7 of the specification would be that they accurately describe the herbicide resistance mechanism of PTA-904; but that the necessary confirming experimental data had not been collected as of the international filing date of the application. The assay that would be used to confirm the resistance mechanism is described in detail in the specification, and when that assay was conducted as described there, the results were in fact as expected.

Written description may, of course, be provided in a “prophetic example.” While the PTA-904 rice line was described in working examples, the AHAS herbicide resistance assay was described prophetically. To the extent that the “prophetic example” of the assay might be germane to the written description requirement, the prophetic example has been fully confirmed by subsequent experimental data, as reported in Dr. Croughan’s December 18, 2002 Affidavit.

To the extent that the herbicide resistance mechanism of PTA-904 might be germane to the question of written description, the specification accurately describes that mechanism.

***(b) A person of ordinary skill in the art could readily distinguish the claimed herbicide-resistant rice plants from other herbicide-resistant rice plants.***

For the reasons given in the May 16, 2003 Amendment, it is respectfully submitted that a person of ordinary skill in the art could readily distinguish the claimed herbicide-resistant rice plants from other herbicide-resistant rice plants. The Office is respectfully requested to review those reasons, which will not be repeated in full here in the interest of brevity. Applicant additionally offers the following observations on this question.

The August 13, 2003 Office Action at page 4 offers three reasons to support this basis for rejection. Each of these three reasons is discussed in turn below:

(I) The Office Action at page 4 said that “the description of the herbicide resistance characteristics of PTA-904 does not adequately describe ‘derivative’ plants.” The present specification gives a clear, unambiguous description of what is considered a “derivative” of a herbicide-resistant plant. See page 31, line 31 to page 32, line 6:

Unless otherwise clearly indicated by context, the "progeny" of a plant includes a plant of any subsequent generation whose ancestry can be traced to that plant.

Unless otherwise clearly indicated by context, a "derivative" of a herbicide-resistant plant includes both the progeny of that herbicide-resistant plant, as the term "progeny" is defined above; and also any mutant, recombinant, or genetically-engineered derivative of that plant, whether of the same species or of a different species; where, in either case, the herbicide-resistance characteristics of the original herbicide-resistant plant have been transferred to the derivative plant. Thus a "derivative" of a rice plant with a resistant AHAS enzyme would include, by way of example and not limitation, any of the following plants that express the same resistant AHAS enzyme: F<sub>1</sub> progeny rice plants, F<sub>2</sub> progeny rice plants, and F<sub>30</sub> progeny rice plants.

The quoted passage gives a clear description of “derivatives.”

The Office has withdrawn the earlier § 112, second paragraph rejection, thereby implicitly acknowledging that the quoted portion of the specification provides

a clear definition of “derivative.” But if a definition provided in a specification is clear, then it logically follows that the same definition must set forth a written description of the term being defined. For the same reasons that have been accepted by the Office as to why the term “derivative” is definite – namely, that the specification provides a detailed definition – it is respectfully submitted that the specification provides a written description of the term “derivative.”

(ii) The Office Action at page 4 said that “[i]f such a ‘derivative’ rice plant is heterologous for AHAS with two different mutations, the herbicide resistance characteristics of PTA-904 would be masked.”

Applicant interprets this remark as an assertion that, if a rice plant was heterozygous for both the mutant, herbicide-resistant AHAS allele of PTA-904 and a different mutant, herbicide-resistant AHAS allele, then it might be less than straightforward to tell whether such a hybrid was indeed a “derivative” of PTA-904.

It is respectfully submitted that this assertion, even if correct, is not pertinent to the question of written description. Furthermore, it is respectfully submitted that the assertion is factually incorrect. Finally, it is respectfully submitted that, as a practical matter, such a scenario is exceedingly unlikely to arise “innocently” anyhow.

(A) The assertion is not pertinent to the question of written description. As the Office has recognized, the principal question underlying the written description requirement is the following: “To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.” M.P.E.P. § 2163, subpart (I), second paragraph, citation omitted. There simply is no requirement that the inventor describe every way in which the presence of his invention might be masked by the addition of other factors, and to distinguish whether the invention is present in such a cryptic situation.

To give a hypothetical analogy: Suppose that an inventor discovered a completely new and unobvious red pigment, useful in paints, and that the inventor otherwise gives a complete written description of that pigment. Is the written description somehow defective because someone might hypothetically mix in a chemically different pigment having a similar hue, perhaps making it more difficult to tell whether the novel pigment is present? The present description gives an explicit description of hybrids, crosses, backcrosses, etc., and therefore shows that the inventor was in possession of the invention as claimed. See, e.g., the present specification at page 31, line 31 to page 32, line 6.

**(B)** It is respectfully submitted that the Office's assertion is factually incorrect. One of skill in the art could readily tell whether a hybrid between PTA-904 and a different source of herbicide resistance had been made. For one thing, herbicide resistance profiles for different mutants typically differ. By observing a hybrid's profile of resistance to various AHAS-acting herbicides, one could generally tell whether different sources of resistance were present. For another thing, using known techniques of genetics (e.g., the segregation of traits in  $F_1$ ,  $F_2$ , and succeeding generations, meiotic recombination, and the like), a person of ordinary skill in the art could readily determine whether different sources of resistance were present in a given plant, without undue experimentation.

**(C)** But perhaps the most compelling reason is the following: Even if one assumed, for the sake of argument, that the assertion were factually correct -- i.e., even if one assumed, for the sake of argument, that a hybrid also having another source of herbicide resistance could "mask" the resistance characteristics of PTA-904 -- it should nevertheless be realized that such a situation would be highly unlikely to arise "innocently." It is respectfully submitted that, as a matter of policy, the PTO should not examine patent claims in a way that could provide a road map to encourage infringers to adopt the core of a claimed invention -- that is, not to design around the claimed invention, but to adopt its very core -- and yet avoid liability for infringement.

If the Office's assertion were not withdrawn, then a would-be infringer could hypothetically read the prosecution history of the present application, conclude that derivatives incorporating the disclosed, novel source of herbicide resistance might fall outside the scope of the claims, and then proceed to prepare such derivatives. The infringer would thus incorporate the core of the present invention into rice plants that would nevertheless have the PTO's imprimatur as being noninfringing. As a matter of policy, the Office should not encourage such situations.

Applicant repeats that this hypothetical situation does not involve the classical situation of "designing around" a patented invention, which the courts have interpreted the patent laws to encourage (at least in certain circumstances). To the contrary, this situation would be one in which the prosecution history would give the would-be infringer a road map as to how to appropriate the core of the patented invention, and yet avoid liability for infringement – merely make a derivative of PTA-904, a derivative that inherits the mutant AHAS resistance trait from PTA-904. So long as the resulting plant is a derivative, not PTA-904 itself, the would-be infringer would be in the clear. Such a result should not be permitted. The Office's prior statements concerning written description should be withdrawn.

Looking at the same topic from a different perspective, a little reflection will reveal that the situation the Office has identified is one that is most unlikely to arise "innocently." Suppose that, for commercial ends, and without the permission of the patentee, someone attempted to prepare a derivative of PTA-904 that also incorporated another source of herbicide resistance. Further suppose that, at least in a superficial sense, this other source of resistance might be considered to "mask" the herbicide resistance traits of PTA-904. The motivation underlying such efforts could only be to exploit the novel herbicide resistance characteristics of PTA-904, without incurring liability for patent infringement. There are three sub-possibilities, none of which is consistent with an "innocent" activity, conducted on a commercial basis, in which there would be genuine confusion as to the source of herbicide resistance. (1) If the alternative source of herbicide resistance has a qualitatively different herbicide

resistance profile, then it will not truly “mask” the PTA-904 source of resistance, and the hypothetical situation identified in the August 13, 2003 Office Action would not exist. (2) If the alternative source of herbicide resistance were qualitatively similar but quantitatively inferior, then the motivation for making the derivative would presumably be to exploit the novel herbicide resistance characteristics of PTA-904, while escaping liability for patent infringement. Without the authorization of the patentee, this would not be an “innocent” activity, and it should not be encouraged. (3) If the alternative source of herbicide resistance had qualitatively similar properties, and if it were somehow sufficiently different that the alternative source itself could avoid infringement, and if its herbicide resistance properties were quantitatively comparable to those of PTA-904, then there would seem to be no reason for the outside party to prepare a hypothesized hybrid for commercial use. So as a practical matter, this situation would not arise in a commercial application.

(iii) The third reason given in the August 13, 2003 Office Action in support of the written description rejection at page 4 is that “Applicant does not describe how the genetic background of PTA-904 influences these herbicide resistance characteristics.”

Again, it is not seen how this raises a written description issue. As discussed above, the disclosure provides a lengthy description of hybrids and other derivatives of PTA-904.

Data obtained since the application was filed confirm that the mutant AHAS from PTA-904 in fact behaves very similarly when incorporated into different genetic backgrounds. Cultivated rice has two principal subspecies, *Oryza sativa indica* and *Oryza sativa japonica*. As shown in the enclosed new Declaration from inventor Dr. Timothy Croughan, the PTA-904 line has now been crossed with numerous other varieties as part of a breeding program. The herbicide resistance phenotype has been essentially constant in the offspring of all these crosses, including varieties of both subspecies, *indica* and *japonica*. Thus the invention works as predicted by the



disclosure in rice varieties and hybrids generally, and does not depend strongly upon the genetic background of a particular derivative.

***Alternative Argument Concerning Certain Independent Claims.***

Strictly in the alternative, this ground of rejection should be withdrawn at least for Claims 31, 54, 129-132, 134-136, 138, 140-142, 157-160, 162-164, 166, and 168-175, and 183-185, each of which contains, in addition to the “derivative” limitation, a further limitation directed to the rice plant with ATCC accession number PTA-904 or progeny of the plant with ATCC accession number PTA-904.

This alternative argument was presented in the May 16, 2003 Amendment, but the August 13, 2003 Office Action did not address it at all. For the reasons given above, it is respectfully submitted that the written description rejection should be withdrawn respecting all Claims. Strictly in the alternative, it is respectfully submitted that the stated grounds of rejection – whether legally sufficient or insufficient with respect to the other Claims – on their face simply do not apply to Claims 31, 54, 129-132, 134-136, 138, 140-142, 157-160, 162-164, 166, and 168-175, and 183-185. At a minimum, it is respectfully submitted that this ground of rejection should be withdrawn for this subset of Claims.

Should the Office disagree, the Office is respectfully requested to explain its reasons, so that a responsive reply might be formulated. It is difficult for the Applicant to prepare an meaningful reply on this point, where the Applicant has previously given a specific traversal of the rejection of this subset of Claims, and the Office has offered no response of any sort. The Office’s attention is respectfully directed to M.P.E.P. § 707.07(f), second paragraph, which states: “Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant’s argument and answer the substance of it.” In the event that this ground of rejection should be repeated, the Office is respectfully reminded that it should “take note of the applicant’s argument and answer the substance of it,” so that a more responsive reply might be made.

***Written description summary.*** For the above reasons, it is respectfully submitted that the written description rejection should be withdrawn. Strictly in the alternative, if the Office should maintain this ground of rejection, the Office is respectfully requested to clarify which of the bases for the written description rejection are still being maintained by the Office, so that Applicant's further reply may properly focus on those points. Further in the alternative, it is respectfully submitted that the written description rejection should be withdrawn at least for those dependent Claims enumerated in the preceding section of this Reply.

### **8. The Enablement Rejection**

All Claims were rejected as containing subject matter that was not enabled by the specification.

If the undersigned has correctly understood the Office's remarks, it appears that the only basis for the enablement rejection that the Office has repeated was that concerning "derivatives," and that the basis for the "derivatives" enablement rejection was essentially the same as the basis for the "derivatives" written description rejection.

If this understanding is incorrect, the Office is respectfully requested to clarify so that a more responsive reply might be made.

If this understanding is correct, then -- for the same reasons as given above in the discussion of written description -- reasons that will not be repeated in the interest of brevity - - it is respectfully submitted that the enablement rejection should be withdrawn as well.

It is not clear whether the Office intended to repeat its earlier assertion that "claim 1 can be read to encompass a rice plant that is a 'derivative' of ATCC accession number PTA-904, but the 'herbicide resistance characteristics of the plant with ATCC accession number PTA-904' can be introduced from another rice plant." If so, please note that the specification provides a detailed definition of what it means for one plant to be a "derivative" of another. See page 31, line 31 to page 32, line 6. Claim 1 requires that the rice plant must, among other things, have herbicide resistance characteristics that may be traced back to the deposited line PTA-904.

Strictly in the alternative, this ground of rejection should be withdrawn at least for Claims 31, 54, 129-132, 134-136, 138, 140-142, 157-160, 162-164, 166, and 168-175, and 183-185, each of which contains, in addition to the “derivative” limitation, a further limitation directed to the rice plant with ATCC accession number PTA-904 or progeny of the plant with ATCC accession number PTA-904. This alternative argument was presented in the May 16, 2003 Amendment, but the August 13, 2003 Office Action did not address it at all. For the reasons given above, it is respectfully submitted that the enablement rejection should be withdrawn respecting all Claims. Strictly in the alternative, it is respectfully submitted that the grounds of rejection of record – whether legally sufficient or insufficient with respect to the other Claims – on their face simply do not apply to Claims 31, 54, 129-132, 134-136, 138, 140-142, 157-160, 162-164, 166, and 168-175, and 183-185. At a minimum, it is respectfully submitted that this ground of rejection should be withdrawn for this subset of Claims.

#### **9. The Prior Art Rejection**

All Claims were rejected under 35 U.S.C. § 102(b) or § 103(a) as being anticipated by, or obvious over Terakawa.

For the reasons given in the May 16, 2003 Amendment – reasons that will not be repeated in the interest of brevity – it is respectfully submitted that the prior art rejections should be withdrawn. For the reasons given in the prior Amendment, it is respectfully submitted that the Terakawa paper on its face is clearly distinguishable from the claimed inventions. Applicant continues to urge this position, and the discussion appearing below should not be construed to the contrary.

The August 13, 2003 Office Action at page 7 stated that the “Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same, material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden

is on the Applicant to provide that the claimed product is different from those taught by the prior art . . . .”

In the interest of accelerating prosecution, to address the Office’s concerns Applicant is currently seeking to obtain samples of the seed mentioned in the Terakawa paper from the authors of that paper. (a) If the seed is available, then herbicide tolerance tests will be conducted to compare directly the herbicide tolerance profiles of the Terakawa rice lines and of PTA-904. Applicant’s prediction is that the herbicide tolerance profiles would be both qualitatively and quantitatively different. (b) Alternatively, it might be the case that this seed is no longer available. If the seed were no longer available, then Terakawa would not be an enabling disclosure with respect to the specific rice lines in question. A nonenabling disclosure cannot anticipate a claimed invention; nor could a nonenabling disclosure make a claimed invention obvious.

For the reasons given in the May 16, 2003 Amendment, it is respectfully submitted that the prior art rejections should be withdrawn. Alternatively, the results of the Terakawa *et al.* inquiry and, if applicable, comparative tests will be submitted to the Office when available.

#### **10. The Provisional Obviousness-Type Double Patenting Rejection over Co-Pending Application S.N. 09/934,973**

All Claims were provisionally rejected under the doctrine of obviousness-type double patenting over certain Claims of co-pending application S.N. 09/934,973.

It is respectfully submitted that this provisional ground of rejection should be withdrawn for any one of the following reasons: (a) The Office did not apply the correct legal standard to the double patenting question. (b) The Office’s conclusion was based on incorrect factual assumptions. (c) Under the correct legal standard, applied correctly to the facts of this case, there is no obviousness-type double patenting.

The same arguments were submitted in the May 16, 2003 Amendment, but the Office did not respond other than in a conclusory fashion to say that “they are not persuasive.”

Should the Office repeat this provisional rejection, the Office is respectfully requested to respond directly to Applicant's arguments, so that a responsive reply might be formulated. It is difficult for the Applicant to prepare a meaningful reply on this point, where the Applicant has previously given a specific traversal of the provisional rejection, and the Office has offered no substantial response. The Office's attention is again respectfully directed to M.P.E.P. § 707.07(f).

For the reasons given below, it is respectfully submitted that this provisional ground of rejection should be withdrawn. But if the Office should instead repeat the provisional ground of rejection, then the Office is specifically requested to:

(a) Clearly articulate the legal standard that the Office has applied, and to cite governing authority in support of that legal standard;

(b) Respond to Applicant's specific arguments below that the Office's conclusions were based on incorrect factual assumptions; and

(c) Respond to Applicant's specific arguments below that when the correct legal standard is applied to the actual facts, there is no obviousness-type double patenting.

(a) The correct legal standard is the following: "does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?" M.P.E.P. § 804, subpart (II)(B)(1), first paragraph.

With all respect, it is difficult to understand what standard was applied in part 20 of the March 10, 2003 Office Action, which was "repeated for the reason of record" on page 8 of the August 13, 2003 Office Action. The March 10, 2003 Office Action said (on page 14):

Copending Application No. 09/934,973 claims a herbicide-resistant rice plant that expresses a functional AHAS enzyme that is resistant to inhibition by at least one herbicide that normally inhibits AHAS. The instant claims are *prima facie* obvious in

view of copending Application No. 09/934,973 because the instant claims are directed to “derivative” rice plants and “progeny” rice plants, rice plants of which the nature of the herbicide-resistance is not taught.

While it is not clear what legal standard this paragraph purports to apply, it does not appear to be that set forth in M.P.E.P. § 804, subpart (II)(B)(1), first paragraph.

Likewise, the August 13, 2003 Office Action asserts at page 8 that “the rice plant that is a ‘derivative’ or progeny of PTA-904 would obviously fall within the scope of the claimed invention at claim 62 of the copending application.” While this statement may be factually correct, it does not apply the correct legal standard.

The correct question legally is not, as the Office Action implicitly asserts, whether some embodiments might fall within the scope of claims pending in both applications. Nor is the correct question whether the scope of a claim in one application might be subsumed within the scope of a claim in the other application. Rather, the correct legal question is “does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?” M.P.E.P. § 804, subpart (II)(B)(1), first paragraph.

(b) The March 10, 2003 Office Action, whose reasons were repeated in the August 13, 2003 Office Action, appeared to base its conclusions on incorrect factual assumptions. While this part of the Office Action is not entirely understood, it seemed to be based on an assumption that the nature of the herbicide resistance of derivatives and progeny was not taught by the present specification.

To the extent that this assumption might have a bearing on the propriety of an obviousness-type double patenting rejection, it is respectfully submitted that the assumption is incorrect. As previously discussed, the specification provides a detailed definition of what it means for one plant to be a “derivative” of another. That discussion will not be repeated here in the interest of brevity, but it is respectfully submitted that the earlier discussion concerning “derivatives” also answers the Office’s contention here. In brief, Claim 1 requires that the rice plant must, among other things, have herbicide resistance characteristics that may be traced back to the deposited line PTA-904.

Furthermore, element (c) of independent Claim 1 specifically requires that “said plant has the herbicide resistance characteristics of the plant with ATCC accession number PTA-904.” Thus the nature of the herbicide resistance characteristics of the derivative Claims is clearly taught by the specification.

(c) Under the correct legal standard, applied correctly to the facts of this case, there is no obviousness-type double patenting, provisional or otherwise. As previously discussed, the correct legal standard is whether any claim in the present application defines an invention that is merely an obvious variation of an invention claimed in the cited application. Furthermore, in considering whether the invention defined in a claim of the present application is an obvious variation of the invention defined in a claim of the cited application, the disclosure of the latter may not be used as prior art. Any obviousness-type double patenting rejection (whether provisional or otherwise) should make clear: both the differences between the inventions defined by the conflicting claims; and the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue is an obvious variation of the invention defined in a claim in the cited application.

Neither Office Action has even attempted to apply this standard to the provisional double-patenting question. To support this ground of rejection, at a minimum the Office should identify at least one specific Claim from the '973 application, and at least one specific Claim from the present application, and then explain why a person of ordinary skill in the art would conclude that the latter would have been obvious in light of the former. It is respectfully submitted, however, that the Office has not done so. It is further respectfully submitted that no claimed invention in the present application would have been obvious in light of any invention claimed in the '973 application.

Whether the PTA-904 embodiment, or embodiments encompassing derivatives of PTA-904, would be covered both by the claims of the present application, and by claims of the '973 application, is simply not relevant to the question of obviousness-type double patenting. A proper obviousness-type double patenting analysis is based on a comparison of the claims, not a comparison of particular embodiments.

For example, Claim 62 of the '973 application currently reads as follows:

62. (once amended) A herbicide-resistant rice plant, wherein:

(a) the growth of said herbicide-resistant plant is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant; and

(b) said herbicide-resistant plant is a derivative of a rice plant obtained by exposing rice plants to mutation-inducing conditions; growing rice plants from the exposed plants, or growing rice plants from progeny of the exposed plants, in the presence of at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant; and selecting for further propagation rice plants that grow without significant injury in the presence of the herbicide; and

(c) said herbicide-resistant plant expresses a functional acetohydroxyacid synthase that is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant;

*provided that excluded from the scope of this Claim is:*

(d) a plant that is the plant with ATCC accession number 97523; and any mutant, recombinant, or genetically engineered derivative of the plant with ATCC accession number 97523 or of any progeny of the plant with ATCC accession number 97523; and any plant that is the progeny of any of these plants; wherein these derivatives of the plant with ATCC accession number 97523 that are excluded from the scope of this Claim are those that have the same herbicide resistance characteristics as the plant with ATCC accession number 97523.

By contrast, Claim 1 of the present application reads as follows:

1. (currently amended) A rice plant wherein:

(a) the growth of said plant is resistant to inhibition by one or more of the following herbicides, at levels of herbicide that would normally inhibit the growth of a rice plant: imazethapyr, imazapic, imazapyr, nicosulfuron, imazaquin, imazamox, metsulfuron methyl, thifensulfuron methyl, tribenuron methyl, pyriithiobac sodium, or a derivative of any of these herbicides; and



(b) said plant is a derivative of the plant with ATCC accession number PTA-904; and

(c) said plant has the herbicide resistance characteristics of the plant with ATCC accession number PTA-904.

The Office has the initial burden of establishing a *prima facie* case of obviousness, just as in any other obviousness rejection; with the exception that obviousness is judged in view of an individual claim of the '973 application -- the remaining teachings of the '973 specification may not be treated as prior art. The Office has not met this initial burden.

Because the Office has not met its initial burden of establishing a *prima facie* case of obviousness over any claim of the '973 application, Applicant has no obligation to rebut the assertion of obviousness. However, in the hope of possibly accelerating prosecution, some comments are offered below why the claimed inventions would not have been obvious over the '973 Claims, taking independent Claim 62 from the '973 application and Claim 1 from the present application as examples.

These two Claims stand in the relation of genus and species. (The Office replied that the relation between the two Claims was more one of genus and subgenus. The distinction between genus/species versus genus/subgenus does not matter for purposes of an obviousness analysis. The relevant point is that the subject matter encompassed by one Claim may be viewed as a subset of the subject matter encompassed by the other, not how the Claims might be viewed for purposes of restriction and election of species under M.P.E.P. Chapter 800.)

A teaching of a genus does not necessarily render an individual species (or a subgenus) obvious. See, e.g., the extended discussion in M.P.E.P. § 2144.08 on this topic. The mere fact that M.P.E.P. § 2144.08 is so lengthy shows that one cannot draw a simple conclusion that a generic teaching necessarily makes a subset (species or subgenus) within the genus obvious. Were there indeed such a simple, black-and-white rule, then M.P.E.P. § 2144.08 could have been written in no more than a paragraph or two.

In particular, there is nothing in Claim 62 of the '973 application that suggests any particular variety or line of herbicide-resistant rice, other than the ATCC 97523 line mentioned in the "negative" limitation of element (d) of that Claim. Keeping in mind that

only the Claim may be considered, and not the specification of the '973 application, a Claim directed generically to herbicide-resistant rice having certain characteristics does not make obvious any particular subset within that genus. If the teachings of the '973 specification were available as prior art, then this conclusion might be different; but in the absence of those teachings, which is how double patenting questions are properly framed, it is difficult to see how any particular variety or line within the scope of the generic claim might be specified with any reasonable expectation of success.

To help illustrate this point, the following "thought experiment" may be helpful: Without reference to anything in the '973 specification other than a selected, single Claim from that application, such as Claim 62 -- attempt to provide an enabling description of a specific variety or line falling within the selected Claim: What are the specific characteristics of the variety or line? How does one make and use the specific variety? What are its specific herbicide resistance characteristics? Probably the only variety or line for which it might be possible to do this would be ATCC 97523, which is the one variety that is specifically mentioned in Claim 62. But ATCC 97523 and its derivatives fall outside Claim 62; indeed, ATCC 97523 is described in Claim 62 only as part of a negative limitation, to specify that ATCC 97523 and its derivatives are outside the scope of the Claim. It is respectfully submitted that it is not possible to give an enabling description of any particular rice variety or line that would fall within the scope of generic Claim 62 of the '973 application, with any reasonable expectation of success, based solely on Claim 62 of the '973 application, and without reference to anything else in the '973 specification.

It is therefore respectfully submitted that no obviousness-type double patenting rejection of any claim in the present application may properly be based on any claim of the '973 application.

Note that nothing in the foregoing argument depends on the particular characteristics of PTA-904. Nevertheless, in the hope of possibly accelerating prosecution, Applicant also notes that PTA-904 has surprising, nonobvious properties – its superior herbicide resistance characteristics could never have been predicted in advance. Even if one did not accept the argument just given; and even if one assumed for the sake of argument that, without

reference to the '973 specification, Claim 62 of the '973 application alone might, with a reasonable expectation of success, allow one to give an enabling description of one or more particular rice varieties or lines that fell within the scope of generic Claim 62 of the '973 application -- even with all these assumptions, it would nevertheless be the case that PTA-904 in particular possesses surprising, nonobvious properties that could not have been predicted with any reasonable expectation of success. A double patenting rejection of the present Claims would therefore still be improper. See, e.g., the results reported in the May 10, 2003 Affidavit of inventor Timothy P. Croughan, filed on May 26, 2003.

(Applicant notes for the record that a terminal disclaimer was preemptively filed in the '973 application over the present application, in order to circumvent possible double patenting issues in the '973 application. In other words, Applicant has voluntarily elected not to contest a hypothetical obviousness-type double patenting rejection of the generic claim over the specific claim, although Applicant does contest the provisional rejection of the specific claim over the generic claim.)

It is respectfully submitted that the provisional obviousness-type double patenting rejection should be withdrawn.

#### **Miscellaneous -- two Information Disclosure Citations**

As requested in the May 16, 2003 Amendment, to help avoid possible future misunderstandings when others might review the file history of this application, the Office is respectfully requested to re-mail an initialed copy of the July 30, 2001 Information Disclosure Citation, marked to show that all references cited on page 4 were considered, not just the first and last entries shown on that page.

The Office's attention is also respectfully directed to the enclosed new Information Disclosure Citation, and to the single reference cited there.

#### **Conclusion**

The Office is respectfully requested to re-mail an initialed copy of the July 30, 2001 Information Disclosure Citation, marked to show that all references cited on page 4 were

considered, not just the first and last entries shown on that page. The Office is also respectfully requested to mail an initialed copy of the enclosed new Information Disclosure Citation.

Allowance of Claims 1-5, 7-9, 11, 13-15, 31, 38, 54, 61, 129-132, 134-136, 138, 140-146, 148-150, 152, 154-160, 162-164, 166, and 168-185 at an early date is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, reading "John H. Runnels", with a horizontal line drawn underneath the signature.

John H. Runnels  
Taylor, Porter, Brooks & Phillips, L.L.P.  
P.O. Box 2471  
Baton Rouge, LA 70821  
(225) 381-0257

Registration No. 33,451

January 8, 2004